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[Intervention Protocol]

Physiotherapy and physiotherapeutical modalities for lateral epicondylitis

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

The objective of this systematic review is to determine the short, intermediate and long-term effectiveness of physiotherapy and various physiotherapeutical modalities for lateral epicondylitis.

BACKGROUND

Lateral epicondylitis (tennis elbow) is a common complaint in primary care. In Dutch general practice the incidence of lateral epicondylitis is estimated at 7 per 1000 patients per year (Verhaar 1992, Miedema 1994). In Sweden the overall prevalence of lateral epicondylitis varies between 1-3%, but this figure increases to 10% for females between 42 years and 46 years of age. The annual incidence of this complaint is 1-3% in the general population (Allander 1974, Chard 1989, Chop 1989). The duration of a typical episode of lateral epicondylitis is reported to be between six months and two years (Murtagh 1988). Finally, lateral epicondylitis results in absenteeism in 10-30% of all patients of which the average duration is 12 weeks (Verhaar 1992, Blanken 1981, Schonk 1985).

In Dutch primary care approximately 30 per cent of all patients with lateral epicondylitis are referred for physiotherapy (Verhaar 1992, Miedema 1994). A wide array of physiotherapy methods are used for treating lateral epicondylitis. Strengthening and stretching exercises of the forearm and wrist, ultrasound, laser, electro(magnetic) field therapy and friction massage for lateral epicondylitis are mainly given by physiotherapists. Choices regarding physiotherapy or physiotherapeutical methods seem to be driven by tradition or are based on trials with a relatively small sample size or poor quality of methods (Beckerman 1993). In an attempt to systematically summarize the available evidence (Labelle 1992) intended to perform a quantitative meta-analysis of 18 randomised controlled trials (RCTs) and evaluated various treatments for lateral epicondylitis, including nine RCTs on physiotherapy. However, they found it impossible to statistically pool the studies because of the considerable variation in treatments, selection criteria and outcome measures. Because of the poor quality of methods and the contradictory results (Labelle 1992) concluded that there was insufficient scientific evidence for any particular type of treatment for lateral epicondylitis.

The review by (Labelle 1992) only covered the RCTs indexed in MEDLINE during 1966-1990, and included only studies published in French or English. According to the current state-of-the-art, a more comprehensive search strategy is advised (Greenhalgh 1997, Meade 1997, Hunt 1997). Thus, RCTs indexed in other bibliographical databases, non-indexed RCTs, RCTs published before 1966 and after 1990 and trials published in other languages than English should be included in a review, as exclusion of these trials might influence the results and conclusions of a review (Gregoire 1995; Egger 1997). Refraining from pooling the data, as Labelle et al. did, is only one of the options available for dealing with the insufficient methodological quality of RCTs (Detsky 1992). There are other ways of incorporating quality scores in the meta-analysis of RCTs containing both the information and the quality of all studies in the review.

Ernst 1994 assessed five randomized clinical trials and four non-randomized clinical trials on the effectiveness of ultrasound for epicondylitis. Just like Labelle 1992, Ernst 1994 only searched in MEDLINE with a restricted period (1980-1992). Ernst 1994 concluded that early reports with poor methodological quality showed promising results, whereas the more recent studies with better designs yielded mostly negative results. The assessment of the methodological quality was not described in this review. Thus, we decided to perform a new, more comprehensive systematic review on the effectiveness of physiotherapy for lateral epicondylitis, using explicit methods for quality assessment, and assessing the possibilities for pooling subsets of comparable studies. Separate analyses of subsets of studies will be conducted, evaluating the influence of prognostic factors, type of physiotherapy, type of control intervention, internal validity of the study, type of outcome measures and timing of follow-up on the effectiveness of physiotherapy for lateral epicondylitis.

OBJECTIVES

The objective of this systematic review is to determine the short, intermediate and long-term effectiveness of physiotherapy and various physiotherapeutical modalities for lateral epicondylitis.

METHODS

Criteria for considering studies for this review

Types of studies

For this systematic review we will include studies that meet the following conditions:
1) Treatment regimens were allocated by a truly random procedure (Schulz 1994).
2) Results have been published as a full report before April 1998.
No restrictions will be made concerning the language of publication (Moher 1996, Gregoire 1995).

Types of participants

3) Patients with lateral epicondylitis. This should at least involve identification of lateral elbow pain, increased by pressure on the lateral epicondyl, and with pain on resisted dorsiflexion.

Types of interventions

4) At least one of the treatments has included physiotherapy. Physiotherapy has to be contrasted with either placebo, no treatment (waiting list control group), injection, another physiotherapeutical treatment or "other" (none of the previously mentioned) conservative treatment. Studies comparing physiotherapy with surgical treatment will be excluded. Trials in which all intervention

groups receive physiotherapy (physiotherapeutical modality) as a co-intervention will be excluded.

Types of outcome measures

5) At least one clinically relevant outcome measure (pain, global improvement, elbow specific functional status, grip strength, generic functional status or sick leave) was included;
6) Follow-up was at least 1 day.

Search methods for identification of studies

One reviewer (NS) will search computerised bibliographical databases (MEDLINE 01/1966 - 01/1999, EMBASE 01/1988 - 01/1999, and CINAHL 01/1982 - 01/1999) without language restrictions, using adaptations of the highly sensitive Cochrane Collaboration search strategy, which aims to identify all randomised controlled trials (Mulrow 1997). The search strategy used to identify RCTs will include the following keywords: randomised controlled trials, controlled clinical trials, random allocation, double blind, single blind, experiments, multicenter trials and related free text words. Subject headings and textwords used to identify lateral epicondylitis will be: elbow, elbow joint, tendinitis, tennis elbow, epicondylitis. Subject headings and textwords to identify the intervention will be: physiotherapy, physical treatment, physical therapy, physical exercise, rehabilitation, ultrasonic (therapy), ultrasound (therapy), strengthening, stretching, laser (therapy), short wave (therapy), electro (therapy), electromagnetic (therapy), iontophoresis, TENS and manipulation. The Cochrane Controlled Trial Register of the Cochrane Library will be searched for RCTs on epicondylitis (Cochrane Controlled Trial Register 1998). In order to retrieve additional references an additional search for systematic reviews will be carried out in EMBASE and MEDLINE (Hunt 1997). Furthermore, the Current Contents database will be searched, and the references from all retrieved articles will be screened (citation tracking). Finally, a computer aided search will be carried out in the trial register of the Cochrane field of 'Rehabilitation & Related Therapies'. To determine whether a study should be included, title, keywords and abstract of all identified hits of the electronic bibliographical databases will be assessed by two reviewers (NS and WJJA). They will decide independently on the eligibility of the article according to the predetermined selection criteria. If there is any doubt, the article will be retrieved and read. Disagreements between the reviewers will be discussed in a consensus meeting. In case of non-consensus between the reviewers, a third reviewer (LMB) will decide if the study is eligible.
Database: MEDLINE search strategy <1966 to January 1999>

1 randomized controlled trial.pt.
2 controlled clinical trial.pt.
3 randomized controlled trials.sh.
4 random allocation.sh.
5 double blind method.sh.
6 single blind method.sh.
7 1 or 2 or 3 or 4 or 5 or 6
8 (animal not (human and animal)).sh.
9 7 not 8
10 clinical trial.pt.
11 exp clinical trials/
12 (clin$ adj25 trial$).ti,ab.
13 ((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).ti,ab.
14 placebos.sh.
15 placebo$.ti,ab.
16 random$.ti,ab.
17 research design.sh.
18 volunteer$.ti,ab.
19 10 or 11 or 12 or 12 or 13 or 14 or 15 or 16 or 17 or 18
20 19 not 8
21 20 not 9
22 9 or 21
23 tendonitis.sh.
24 elbow.sh.
25 elbow joint.sh.
26 24 or 25
27 23 and 26
28 tennis elbow.sh
29 27 or 28
30 epicondylitis.tw.
31 elbow.tw.
32 29 or 30 or 31
33 22 and 32
34 physical therapy.sh.
35 physical$.tw.
36 physio$.tw.
37 exercise.sh.
38 exercis$.tw.
39 rehabilitation.sh.
40 rehabilitation$.tw.
41 ultrasonic therapy.sh.
42 ultrasonics.sh.
43 ultras$.tw.
44 strengthening.tw.
45 stretching.tw.
46 laser$.tw.
47 short wave therapy.sh.
48 short wave therapy.tw.
49 short wave$.tw.
50 tens.tw.
51 electr$.tw.
52 iontophor$.tw.
53 manipulat$.tw.
54 surgery.sh.
55 surgery.tw.

56 cryotherapy.tw.
57 or/34-56
58 33 and 57
Database: EMBASE search strategy <1966 to January 1999>

1 clinical article.sh.
2 clinical study.sh.
3 clinical trial.sh.
4 controlled study.sh.
5 randomized controlled trial.sh.
6 major clinical study.sh.
7 double blind procedure.sh.
8 multicenter study.sh.
9 single blind procedure.sh.
10 phase 3 clinical study.sh.
11 phase 4 clinical study.sh.
12 crossover procedure.sh.
13 placebo.sh.
14 or/1-13
15 allocat$.ti,ab.
16 assign.ti,ab.
17 blind$.ti,ab.
18 (clinic$ adj25 (study or trial)).ti,ab.
19 compar$.ti,ab.
20 control$.ti,ab.
21 cross?over.ti,ab.
22 factorial$.ti,ab.
23 follow?up.ti,ab.
24 placebo$.ti,ab.
25 prospectiv$.ti,ab.
26 random$.ti,ab.
27 ((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).ti,ab.
28 trial$.ti,ab.
29 (versus or vs).ti,ab.
30 or/15-29
31 14 or 30
32 human.sh.
33 nonhuman.sh.
34 animal.sh.
35 animal experiment.sh.
36 33 or 34 or 35
37 32 and 36
38 31 not 36
39 31 and 37
40 38 or 39
41 tendonitis.sh.
42 elbow.sh.
43 elbow joint.sh.
44 42 or 43
45 41 and 44
46 tennis elbow.sh
47 45 or 46
48 epicondylitis.tw.
49 elbow.tw.
50 47 or 48 or 49
51 40 and 50
52 exercise.sh.
53 exercis$.tw.
54 strengthening.tw.
55 stretching.tw.
56 stretching.sh.
57 laser$.tw.
58 short wave$.tw.
59 tens.tw.
60 physio$.tw.
61 physical$.tw.
62 physiotherapy.sh.
63 rehabilitation.sh.
64 rehabilitation$.tw.
65 ultraso$.tw.
66 ultrasound therapy.sh.
67 ultrasound.sh
68 electr$.tw.669 iontophor$.tw.
70 manipulat$.tw.
71 surgery.sh.
72 surgery.tw.
73 cryotherapy.sh.
74 cryo$.tw.
75 or/52-74
76 51 and 75

Data collection and analysis

Table 1 shows the criteria used for methodological quality assessment, consisting of internal validity criteria, descriptive criteria and statistical criteria. The descriptive and statistical criteria refer to the external validity of the study and are used to identify homogeneous subgroups and conduct sensitivity analyses. This criteria list is a modified version of a list that has already been used in a number of systematic reviews in the field of physiotherapy (Windt 1995, Heijden 1997, Tulder 1997, Vet 1997) and includes all criteria of the list of Jadad 1996, Schulz 1994, and Verhagen 1998. For this review, the description of the methodological criteria items was adjusted for application to lateral epicondylitis and physiotherapy.

Table 1 : Criteria for the methodological assessment of randomised clinical trials†

Validity criteria (for complete study)

Vs1 Randomisation: adequate procedure for generation of a random number sequence

Vs2 Randomisation: concealed random allocation of treatments, by an independent person not responsible for determining eligibility of patients

Vs3 Baseline similarity regarding age, duration of complaints, neck and shoulder complaints, and baseline values of main outcome measure(s)*
Vs4 Co-interventions: control for co-interventions in design
Vs5 Co-interventions: reported for each group separately
Vs6 Adherence to interventions: > 70% in index group, and in placebo-controlled trials also in reference groups
Vs7 Care provider was blinded
Vs8 Patient was blinded
Vs9 Satisfaction of the patients: reported for each group separately
Vs10 Withdrawals and drop-outs: < 20% for short term follow-up (< 6 weeks) and < 30% for intermediate term (6 weeks < 6 months) and long term follow-up (> 6 months) and no substantial bias (inequality between groups; reason for withdrawal/drop-out)
Vs11 Identical timing of outcome assessment for all intervention groups
Vs12 Intention-to-treat analysis
(* = assessed per outcome measure)
Validity criteria (per outcome measure)
Vo1 Outcome assessor was blinded for the outcome measurements: pain, global improvement, elbow specific functional status, grip strength and generic functional status*
Vo2 Valid outcome measurements: pain, global improvement, elbow specific functional status, grip strength and generic functional status*
Vo3 Relevant outcome measurements: pain, global improvement, elbow specific functional status, grip strength and generic functional status*
(* = assessed per outcome measure)
Descriptive criteria
D1 Specification of eligibility criteria
D2 Baseline similarity regarding age, duration of complaints, neck and shoulder complaints, and baseline values of main outcome measure(s)*
D3 Description of interventions: adequate description of type, modality, application technique, intensity, duration and number or frequency of sessions for both the index intervention and reference groups
D4 Adverse effects described and attributed to allocated treatment, or explicit report of 'no adverse effects'
D5 Short term follow-up: outcome assessment at the end of the intervention period (or < 6 weeks)
D6 Intermediate term follow-up: outcome assessment > 6 weeks and < 6 months
D7 Long term follow-up: outcome assessment > 6 months after randomisation
(* = assessed for main outcome measure)
Statistical criteria
S1 Sample size: to be presented at randomisation and for moments of follow-up
S2 Presentation of point estimates and distribution measures, for each important outcome measure separately

† Description of the criteria, original data-extraction form and instructions for their use are available on request from the first author

All articles eligible for the review will be blinded for authors, journal and year of the trial. Included articles will be independently assessed on methodological quality by two blinded reviewers (NS and HA). The success of blinding will be determined by asking both reviewers to attempt to identify the author(s), journal and year of the trial. Initial disagreement between the reviewers about the assessment of the methodological quality of the articles will be calculated per criteria item and expressed as percentage agreement and kappa. (Cohen 1960, Brennan 1992) In a consensus meeting disagreements about the assessment of the methodological quality of the articles will be discussed. If consensus can not be reached, a third reviewer (WJJA) will make the final decision. For studies published in other languages than English, German or Dutch, the help of a native speaker or translator will be sought. As an assessment by different reviewers might affect the accuracy of quality assessment and data extraction, these studies will be indicated.

To determine the internal validity of the study, for each validity criterion the presence of sufficient information and the likelihood of potential bias will be evaluated. If sufficient information is available and bias is considered unlikely, the criterion will be rated positive ('yes'). If bias is considered likely, the criterion will be rated negative ('no'). When insufficient information is given, the criterion will be rated as inconclusive ('don't know'). A total score for internal validity of the study ('study validity score') will be calculated, by summing up the number of positive criteria. Equal weights will be applied, resulting in a validity score with a range of 0 to 10, higher scores indicating lower likelihood of bias. In addition, per outcome measure additional points will be applied for adequate blinding of measurement, and for validity and relevance of the outcome measure.

Two blinded reviewers (NS and HA) will independently extract the data regarding the interventions, type of outcome measures, follow-up, loss to follow-up and outcomes. The various outcome measures will be presented separately. The results of each RCT will be expressed as odds ratio's with corresponding 95% confidence interval for dichotomous data, and as standardized mean differences for continuous data. (Rosenthal 1994, Mulrow 1997, Lau 1997) Analyses will be performed for the short-term, intermediate-term and long-term effect of physiotherapy for lateral epicondylitis separately. Pooling will only be performed if sufficient statistical and clinical homogeneity exist.

Pre-planned stratified analyses are:

I) Character of control groups: Index group physiotherapeutic treatment(s) versus control group of: a) other physiotherapeutic treatment(s), b) other conservative treatment(s) (e.g., oral medication or injection) c) placebo treatment(s) and d) no treatment(s) / waiting list;

II) Validity score: Low validity trials versus high validity trials. (Moher,1998;609) Cut-off point: 50% of the validity criteria are

rated positive (= high validity trial). In addition, sensitivity analyses will be performed for each validity criterion separately.
III) Type of physiotherapeutic intervention: Exercises, ultrasound therapy, electromagnetic field therapy, laser and 'other forms of physiotherapy' separately;
IV) Prognostic factors: a) Lateral epicondylitis with additional neck and shoulder complaints versus lateral epicondylitis without neck or shoulder complaints and b) duration of elbow complaints: acute (< 6 weeks), subacute (6 weeks to 13 weeks), chronic (> 13 weeks);

As reports on subgroup analyses within trials are often lacking, these stratified analyses will be conducted using between-study comparisons.

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* *Indicates the major publication for the study*

WHAT'S NEW

Date	Event	Description
28 May 2008	Amended	Converted to RM5. CMSG ID C144-P

HISTORY

Protocol first published: Issue 2, 1999

DECLARATIONS OF INTEREST

None known

SOURCES OF SUPPORT

Internal sources

- 4) Department of Epidemiology and Preventive Medicine, Australia.
- 3) Finnish Institute for Occupational Health, Finland.
- 2) Tampere Occupational Health Centre, Finland.
- 1) Institute for Research in Extramural Medicine, Netherlands.

External sources

- No sources of support supplied